IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS
DALLAS DIVISION

GALDERMA LABORATORIES, L.P., GALDERMA S.A., and DERMALOGIX PARTNERS, INC., Plaintiffs, v. PERRIGO CO. and PERRIGO ISRAEL PHARMACEUTICALS LTD., Defendants.	Civil Action No. 3:09-cv-02322-M
PERRIGO ISRAEL PHARMACEUTICALS LTD. Counterclaim Plaintiff, v. GALDERMA LABORATORIES, L.P., GALDERMA S.A., DERMALOGIX PARTNERS, INC., PANDA PHARMACEUTICALS, LLC and UNIV. OF TENNESSEE RESEARCH FOUNDATION, Counterclaim Defendants.	Civil Action No. 3:09-cv-02322-M

ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendant/Counterclaim Plaintiff Perrigo Israel Pharmaceuticals, Ltd. ("Perrigo Israel") and Defendant Perrigo Company ("Perrigo Co.") (collectively, "Perrigo"), by way of Answer and Counterclaims to the Complaint of Plaintiffs/Counterclaim Defendants Galderma Laboratories, L.P., Galderma S.A., and Dermalogix Partners, Inc. (collectively "Plaintiffs") and

to Counterclaim Defendants Panda Pharmaceuticals, LLC and University of Tennessee Research Foundation, allege as follows:

THE PARTIES

COMPLAINT:

1. Plaintiff Galderma Laboratories, L.P. is a Texas Limited Partnership, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177. As part of its business, Galderma Laboratories, L.P. is involved in the research, development, marketing, and sale of pharmaceutical products.

ANSWER: On information and belief, Perrigo admits that Galderma Laboratories, L.P. has a place of business at 14501 North Freeway, Fort Worth, Texas 76177. Perrigo is without sufficient knowledge to admit or deny the remaining allegations of this paragraph, and therefore denies same.

COMPLAINT:

2. Plaintiff Galderma S.A. is a Swiss Corporation, having a principal place of business at World Trade Center, Avenue de Gratta-Paille 2, Case Postale 453, CH-1000 Lausanne 30 Grey, Switzerland. As part of its business, Galderma S.A. is involved in the research, development, marketing, and sale of pharmaceutical products.

ANSWER: Perrigo is without sufficient knowledge to admit or deny the allegations of this paragraph, and therefore denies same.

COMPLAINT:

3. Plaintiff Dermalogix Partners, Inc. ("Dermalogix") is a Maine corporation, having a principal place of business at U.S. Route 1, P.O. Box 1510, Scarborough, Maine 04074-9745. As part of its business, Dermalogix is involved in the research and development of pharmaceutical products.

ANSWER: Perrigo is without sufficient knowledge to admit or deny the allegations of this paragraph, and therefore denies same.

COMPLAINT:

4. On information and belief, Defendant Perrigo Co. ("Perrigo Co.") is a Michigan corporation, having a principal place of business located at 515 Eastern Avenue, Allegan, Michigan 49010, and is engaged in the manufacture and sale of pharmaceutical products.

ANSWER: Admitted.

COMPLAINT:

5. On information and belief, Defendant Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel") is an Israeli corporation, having a principal place of business located at 29 Lehi Street, Bnei Brak 51200, Israel. On information and belief, Perrigo Israel manufactures bulk pharmaceutical products.

ANSWER: Perrigo admits that Perrigo Israel Pharmaceuticals Ltd. ("Perrigo Israel") is an Israeli corporation, having a place of business located at 29 Lehi Street, Bnei Brak 51200, Israel. Perrigo denies the remaining allegations of this paragraph.

COMPLAINT:

6. On information and belief, Perrigo Israel is a wholly-owned subsidiary of Perrigo Co.

ANSWER: This paragraph contains legal conclusions for which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo Israel operates as a subsidiary of Perrigo Company. Perrigo denies the remaining allegations of this paragraph.

COMPLAINT:

7. On information and belief, Perrigo Israel is controlled by and/or is an agent of Perrigo Co.

ANSWER: Denied.

COMPLAINT:

8. On information and belief, Perrigo Israel conducts its North American operations, in part, through Perrigo Co.

ANSWER: Denied.

JURISDICTION AND VENUE

COMPLAINT:

9. This action arises under the patent laws of the United States of America, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Plaintiffs' Complaint is for alleged patent infringement and that this Court has subject matter jurisdiction over Plaintiffs' infringement claim against Perrigo Israel. Perrigo denies the remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claim against Perrigo Co.

COMPLAINT:

10. Upon information and belief, Defendant Perrigo Co., as reported in its 2009 Annual Report, engages in the manufacture and sale of a range of generic pharmaceutical products within the United States generally and the State of Texas specifically, including to Wal-Mart, CVS, Krogers, Safeway, Dollar General, Sam's Club, Costco and Walgreens pharmacy stores within this District.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo does not contest personal jurisdiction for purposes of this action only. Perrigo denies the remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claim against Perrigo Co.

COMPLAINT:

11. Perrigo Co. is subject to personal jurisdiction in this District by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Texas law, its substantial and continuing contacts with the State, and its knowledge that a Texas Limited Partnership located in this District would be injured by its actions.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo does not contest personal jurisdiction for purposes of this action only. Perrigo denies the remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claim against Perrigo Co.

COMPLAINT:

12. Upon information and belief, Defendant Perrigo Israel, as reported in its 2009 Annual Report, engages in the manufacture and sale of a range of generic pharmaceutical products purposefully availed to the United States generally and the State of Texas specifically, including sales to Wal-Mart, CVS, Krogers, Safeway, Dollar General, Sam's Club, Costco and Walgreens pharmacy stores within this District.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo does not contest personal jurisdiction for purposes of this action only. Perrigo denies the remaining allegations contained in this paragraph, including that subject matter exists with respect to Plaintiffs' infringement claim against Perrigo Co.

COMPLAINT:

13. On information and belief, Perrigo Israel, according to Perrigo Israel's profile in Dun & Bradstreet Israel Ltd., develops and manufactures generic topical drugs for the U.S. market.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo does not contest personal jurisdiction for purposes of this action only. Perrigo denies the remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claim against Perrigo Co.

COMPLAINT:

14. On information and belief, Perrigo Israel, according to its Corporate Profile, develops and manufactures generic topical drugs at its Yeruham, Israel manufacturing location for the U.S. market as part of the Perrigo Rx Pharmaceuticals Group.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo does not contest personal jurisdiction for purposes of this action only. Perrigo denies the remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claim against Perrigo Co.

COMPLAINT:

15. On information and belief, generic topical drugs developed and manufactured by Perrigo Israel for the U.S. market includes cetirizine tablets and syrup, clobetasol foam, halobetasol ointment and cream, and mesalamine rectal suspension enema.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo does not contest personal jurisdiction for purposes of this action only. Perrigo denies the remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claim against Perrigo Co.

COMPLAINT:

16. On information and belief, annual U.S. sales of cetirizine (brand name Zyrtec) tablets and syrup are approximately $500 million, making it one of the top selling drugs in the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo does not contest personal jurisdiction for purposes of this action only. Perrigo denies the remaining allegations contained in this

paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claim against Perrigo Co.

COMPLAINT:

17. On information and belief, Perrigo Israel has approximately 36% of the generic market for cetirizine tablets and syrup.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo does not contest personal jurisdiction for purposes of this action only. Perrigo denies the remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claim against Perrigo Co.

COMPLAINT:

18. On information and belief, Perrigo Co. acts as an agent of Perrigo Israel with respect to the generic topical drugs developed and manufactured by Perrigo Israel for the U.S. market.

ANSWER: Denied.

COMPLAINT:

19. On information and belief, Perrigo Israel regularly transacts business within this District, including but not limited to shipping generic pharmaceuticals to Perrigo Co. from locations outside the United States for distribution by Perrigo Co. within the United States generally, and within this District specifically, including among others, generic cetirizine.

ANSWER: Denied.

COMPLAINT:

20. Perrigo Co.'s acts and contacts with this District, as an agent of Perrigo Israel, are attributable to Perrigo Israel for jurisdictional purposes.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo does not contest personal jurisdiction for purposes of this action only. Perrigo denies the remaining allegations contained in this

paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claim against Perrigo Co.

COMPLAINT:

21. Perrigo Israel is subject to personal jurisdiction in this District by virtue of, *inter alia*, its conduct of business in this District, its purposeful availment of the rights and benefits of Texas law, its substantial and continuing contacts with the State, and its knowledge that a Texas Limited Partnership located in this District would be injured by its actions.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo does not contest personal jurisdiction for purposes of this action only. Perrigo denies the remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claim against Perrigo Co.

COMPLAINT:

22. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(c) and 1400(b). For example, Plaintiff Galderma Laboratories, L.P. is located in this District, and Galderma's witnesses and documents will be material to this litigation. As another example, venue is appropriate in this District because the claims asserted herein arise out of an act of patent infringement (i.e., Perrigo Co. and Perrigo Israel's filing of the ANDA and issuance of the Paragraph IV Certification) purposefully targeting a resident of this District (Galderma Laboratories, L.P.). As a further example, 21 U.S.C. § 355(j)(5)(C)(i)(II) establishes this District as the only proper venue in which Perrigo Co. and Perrigo Israel could file suit seeking a declaration of non-infringement in connection with the ANDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo does not contest venue for purposes of this action only. Perrigo denies the remaining allegations contained in this paragraph.

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

COMPLAINT:

23. On October 26, 1999, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 5,972,920 (the "920 patent"), entitled "Formulation Containing a Carrier, Active Ingredient, and Surfactant for Treating Skin Disorders," to Dermalogix Partners, Inc., the

assignee of the named inventor William E. Seidel. Dermalogix is the current assignee of the '920 patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that U.S. Patent No. 5,972,920 ("the '920 patent"), which is entitled "Formulation Containing A Carrier, Active Ingredient, and Surfactant For Treating Skin Disorder," identifies, on its face, William E. Seidel as the purported inventor. Perrigo further admits that, according to the online records of the United States Patent and Trademark Office ("USPTO"), the '920 patent issued on October 26, 1999 and Dermalogix Partners, Inc. is currently the listed assignee of the '920 patent. Perrigo denies any suggestion that the '920 patent was duly and legally issued, as well as any suggestion that the '920 patent is valid or enforceable. Perrigo denies the remaining allegations of this paragraph.

COMPLAINT:

24. Plaintiff Dermalogix granted Plaintiff Galderma an exclusive sublicense to the '920 Patent to make, distribute, market, sell, and use a clobetasol propionate spray for the treatment of skin disorders including psoriasis. Galderma's exclusive license included the right to sublicense. A copy of the '920 Patent is attached hereto as Exhibit A.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that what appears to be a copy of the '920 patent is attached to the Complaint at Exhibit A. Perrigo is without sufficient knowledge to admit or deny the remaining allegations of this paragraph, and therefore denies same.

COMPLAINT:

25. The '920 Patent is valid, enforceable and has not expired.

ANSWER: Denied.

COMPLAINT:

26. On October 27, 2005, the United States Food and Drug Administration ("FDA") approved New Drug Application ("NDA") No. 21-835 for clobetasol propionate spray .05% for topical application. Galderma is the holder of NDA No. 21-835 for clobetasol propionate spray .05% for topical application, which Galderma sells under the name Clobex®.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that according to FDA's online records, Galderma Labs LP is listed as the current "applicant" for New Drug Application ("NDA") No. 21-835. Perrigo further admits that according to FDA's online records, on or about October 27, 2005, FDA sent an approval letter to "Dow Pharmaceutical Sciences" regarding NDA No. 21-835, which stated in part: "This new drug application provides for the use of CLOBEX (clobetasol propionate) Spray, 0.05% . . . ." Perrigo is without sufficient knowledge to admit or deny the remaining allegations of this paragraph, and therefore denies same.

COMPLAINT:

27. The '920 patent is listed in the FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (known as the "Orange Book") as covering Clobex® clobetasol propionate spray .05% for topical application.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that according to FDA's online records, the '920 patent is currently listed in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as "the Orange Book") in connection with NDA No. 21-835 for Clobex® (clobetasol propionate) Spray, 0.05%. On information and belief, FDA listed the '920 patent in connection with NDA No. 21-835 because it was requested by the NDA-holder to do so. Perrigo is without sufficient information to admit or deny the

remaining allegations of this paragraph, and therefore denies them, including denying any suggestion that the '920 patent covers Clobex® Spray, 0.05%.

COMPLAINT:

28. On information and belief, Defendants reviewed the '920 patent and certain commercial and economic information relating to Clobex®, including estimates of the revenues generated by the sale of Clobex®, and decided to file an Abbreviated New Drug Application ("ANDA"), seeking approval to market clobetasol propionate spray 0.05%.

ANSWER: Perrigo admits that Perrigo Israel submitted an Abbreviated New Drug Application ("ANDA"), pursuant to 21 U.S.C. § 355(j), seeking FDA approval to commercially manufacture, use and sell clobetasol propionate spray, 0.05%, prior to the expiration of the '920 patent, and that Perrigo Israel's ANDA contains a so-called "paragraph IV certification" to the '920 patent. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

29. On information and belief, Defendants submitted to the FDA ANDA No. 91-167 to seek approval to engage in the commercial manufacture, use, and sale of clobetasol propionate spray 0.05% prior to the expiration of the '920 patent.

ANSWER: Perrigo admits that Perrigo Israel submitted ANDA No. 91-167 seeking FDA approval to commercially manufacture, use and sell clobetasol propionate spray, 0.05%, prior to the expiration of the '920 patent. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

30. Plaintiffs received a letter dated October 23, 2009 from Defendants notifying them that Perrigo Co. and Perrigo Israel's ANDA No. 91-167 includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV certification") that, in Defendants' opinion, the '920 patent is invalid or not-infringed.

ANSWER: Perrigo admits that Perrigo Israel filed with FDA ANDA No. 91-167 with a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a so-called "paragraph IV certification") that Perrigo Israel seeks FDA approval to engage in the commercial manufacture, use, sale or importation of fluticasone propionate lotion, 0.05%, prior to the expiration of the '920 patent. Perrigo admits that by letter dated October 23, 2009, Perrigo Israel gave written notification to, *inter alia*, Plaintiffs, pursuant to 21 U.S.C. § 355(j)(2)(B), of the paragraph IV certification contained in Perrigo Israel's ANDA No. 91-167 regarding the invalidity, unenforceability and/or non-infringement for both the '920 patent and U.S. Patent No. 5,990,100. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

31. On information and belief, Defendants were necessarily aware of the '920 patent when they filed ANDA No. 91-167 and a Paragraph IV certification.

ANSWER: Perrigo admits that Perrigo Israel submitted ANDA No. 91-167 with a paragraph IV certification to the '920 patent seeking FDA approval to commercially manufacture, use and sell clobetasol propionate spray, 0.05%, prior to the expiration of the '920 patent. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

32. Plaintiffs commenced this action within 45 days of the date that they received Defendant's notice of ANDA No. 91-167 containing the Paragraph IV certification.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that according to online records of this judicial District, Plaintiffs filed the instant action on December 4, 2009. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

33. On information and belief, Defendants intend to continue seeking approval of ANDA No. 91-167 from the FDA and to engage in the commercial manufacture, marketing and sale of clobetasol propionate spray 0.05% (including commercial marketing and sale of such a product in the State of Texas, including this District) in the event that FDA approves ANDA No. 91-167.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo Israel submitted ANDA No. 91-167 seeking FDA approval to commercially manufacture, use and sell clobetasol propionate spray, 0.05%, prior to the expiration of the '920 patent. Perrigo denies the remaining allegations contained in this paragraph.

FIRST CLAIM FOR RELIEF
(Infringement of the '920 Patent by Perrigo Co. and Perrigo Israel)

COMPLAINT:

34. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 33 hereof, as if fully set forth herein.

ANSWER: Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

COMPLAINT:

35. Through the conduct alleged above, Defendants have infringed, and continue to infringe, claims 1-2, 6 and 8-12 of the '920 Patent.

ANSWER: Denied.

COMPLAINT:

36. By filing ANDA No. 91-167 with a Paragraph IV certification seeking FDA approval to engage in the commercial manufacture, use, and sale of clobetasol propionate spray 0.05% prior to the expiration of the '920 Patent, Defendants have infringed the '920 Patent under 35 U.S.C. § 271(e)(2).

ANSWER: Denied.

COMPLAINT:

37. Defendants were aware of the existence of the '920 Patent prior to filing ANDA No. 91-167, but took such action knowing that it would constitute an infringement of the '920 Patent.

ANSWER: Denied.

COMPLAINT:

38. On information and belief, Defendants acted without a reasonable basis or good faith belief that they would not be liable for infringing the '920 Patent.

ANSWER: Denied.

COMPLAINT:

39. Defendants' conduct renders this case "exceptional" as described in 35 U.S.C. § 285.

ANSWER: Denied.

COMPLAINT:

40. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the '920 Patent.

ANSWER: Denied.

AFFIRMATIVE DEFENSES

First Defense

41 The manufacture, use, or sale of the Clobetasol Propionate Spray, 0.05% product described in Perrigo Israel's ANDA has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid or enforceable claim of the '920 patent.

Second Defense

42. Plaintiffs are barred by prosecution history estoppel from presenting an interpretation of the claims of the '920 patent necessary to find infringement.

Third Defense

43. The claims of the '920 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

Fourth Defense

44. This Court lacks subject matter jurisdiction over Plaintiffs' claim for patent infringement against Perrigo Co.

Fifth Defense

45. Plaintiffs fail to state a claim upon which relief can be granted under controlling Federal Circuit case law.

Sixth Defense

46. Any additional defenses or counterclaims, including for patent unenforceability, that discovery may reveal.

RESPONSE TO REQUESTED RELIEF

Perrigo denies that Plaintiffs are entitled to any relief as set forth in Paragraphs (A)-(G) of their Complaint, or to any relief whatsoever, and further requests that Plaintiffs' Complaint be dismissed with prejudice and that Perrigo be awarded its attorney fees and costs incurred in defending this suit under 35 U.S.C. § 285.

COUNTERCLAIMS

Parties

1. On information and belief, Galderma Laboratories, L.P. ("Galderma Labs.") purports to be a Texas Limited Partnership, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

2. On information and belief, Galderma S.A. ("Galderma S.A.") purports to be a Swiss Corporation, having a principal place of business at World Trade Center, Avenue de Gratta-Paille 2, Case Postale 453, CH-1000 Lausanne 30 Grey, Switzerland.

3. On information and belief, Dermalogix Partners, Inc. ("Dermalogix") purports to be a Maine corporation, having a principal place of business at U.S. Route 1, P.O. Box 1510, Scarborough, Maine 04074-9745.

4. On information and belief, Panda Pharmaceuticals, LLC ("Panda") purports to be a Tennessee limited liability company, having a principal place of business at 1455 Union Avenue, Memphis, Tennessee 38104.

5. On information and belief, University of Tennessee Research Foundation ("University") purports to be a Tennessee corporation having a principal place of business at 1534 White Avenue, Suite 403, Knoxville, Tennessee 37996.

6. Perrigo Israel Pharmaceuticals, Ltd. ("Perrigo Israel") is a company organized and existing under the laws of Israel having a principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel.

Jurisdiction and Venue

7. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare

Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

8. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

9. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants Galderma Labs., Galderma S.A. and Dermalogix because Galderma Labs., Galderma S.A. and Dermalogix availed themselves of the rights and privileges of this forum by suing Perrigo Israel in this District, and, on information and belief, because Plaintiffs/Counterclaim-Defendants Galderma Labs., Galderma S.A. and Dermalogix conduct substantial business in, and have regular systematic contact with, this District.

10. On information and belief, this Court has personal jurisdiction over Counterclaim-Defendants Panda and University because Counterclaim-Defendants Panda and University do business within this district and/or have substantial contacts in this district.

11. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

Background

A. FDA Approval of New Brand-Name Drugs.

12. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003)

("MMA"), sets forth the rules that the U.S. Food and Drug Administration ("FDA") follows when considering whether to approve both brand-name and generic drugs.

13. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

14. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted. *See* 21 U.S.C. §§ 355(b)(1), (c)(2); 21 C.F.R. §§ 314.53(b), (c)(2).

15. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

B. Generic Competition – Abbreviated New Drug Applications ("ANDAs").

16. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

17. To receive approval of its ANDA, an applicant must, *inter alia*, show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

18. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant must also "certify" that any patent information properly listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

19. When seeking FDA approval to market prior to patent expiration, an ANDA applicant must submit a so-called "paragraph IV" certification asserting that the listed patent is invalid, unenforceable, and/or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

20. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B).

21. If the patent holder brings suit within 45 days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B), FDA cannot approve the ANDA for 30 months, unless the district court enters an order shortening that period. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

22. If the NDA-holder/patent owner does not file suit within 45 days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B), the ANDA applicant can file and maintain a suit for declaratory judgment against the NDA-holder/patent owner to obtain patent certainty. Indeed, Congress explicitly mandated in the MMA amendments to the FFDCA and Hatch-Waxman that an ANDA-filer is entitled to bring and maintain a declaratory judgment action when it is not sued. 21 U.S.C. § 355(j)(5)(C); 35 U.S.C. § 271(e)(5).

23. Under the MMA, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain an action for declaratory judgment against an NDA-holder/patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder/patent owner brought an action for infringement of the patent within the 45-day period; and, (3) the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA if the applicant asserts non-infringement. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

24. Once these three conditions are met, the MMA specifically and unequivocally provides that an ANDA applicant "may, in accordance with section 2201 of Title 28 [of the United States Code] bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II); *see also* 35 U.S.C. § 271(e)(5).

25. An ANDA applicant may exercise its right to file and maintain a declaratory judgment action under the MMA regardless of whether or not the Offer of Confidential Access to Application is accepted.

C. Clobex® (Clobetasol Propionate) Spray, 0.05% And The Patents-In-Suit.

26. On or about October 26, 1999, according to the electronic records of the U.S. Patent and Trademark Office ("USPTO"), U.S. Patent No. 5,972,920 ("the '920 patent"), entitled "Formulation Containing a Carrier, Active Ingredient, and Surfactant for Treating Skin Disorders," issued to inventor William E. Seidel and was assigned to Dermalogix Partners, Inc. A true and correct copy of the '920 patent is attached hereto as Exhibit A.

27. On or about November 23, 1999, according to the electronic records of the USPTO, U.S. Patent No. 5,990,100 ("the '100 patent"), entitled "Composition and Method for Treatment of Psoriasis," issued to E. William Rosenberg, Thomas M. Glenn, Robert B. Skinner, Jr. and Patricia W. Noah, and was assigned to Panda Pharmaceuticals, L.L.C. and The University of Tennessee Research Corporation. A true and correct copy of the '100 patent is attached hereto as Exhibit B.

28. On information and belief, Galderma Labs. is the current applicant for approved NDA No. 21-835 for Clobex® (clobetasol propionate) Spray, 0.05%.

29. On information and belief, Dow Pharmaceutical Sciences, Inc. ("Dow") was the original "applicant" for NDA No. 21-835.

30. On information and belief, Dow and/or Galderma Labs. submitted information on the '920 and '100 patents to FDA for listing in the Orange Book. By virtue of that submission, FDA listed the '920 and '100 patents in the Orange Book in connection with the approved NDA for Clobex® Spray, 0.05%.

31. The listing of the '920 and '100 patents in the Orange Book alone objectively creates the necessary case or controversy and subject matter jurisdiction for an ANDA-filer to file and maintain a declaratory judgment action if it is not sued within the 45-day period of 21 U.S.C. § 355(j)(5)(B)(iii).

D. Perrigo Israel's Clobetasol Propionate Spray, 0.05% ANDA.

32. Perrigo Israel filed an ANDA with the FDA seeking generic approval for clobetasol propionate spray, 0.05%. FDA assigned Perrigo Israel's ANDA No. 91-167.

33. Perrigo Israel's ANDA references Galderma Labs.'s NDA No. 21-835.

34. Because Perrigo Israel's ANDA seeks FDA approval to market its generic clobetasol propionate spray, 0.05% product before expiration of both of the patents listed in the Orange Book, Perrigo Israel's ANDA includes a paragraph IV certification for the '920 and '100 patents.

35. In accordance with 21 U.S.C. § 355(j)(2)(B), Perrigo Israel provided, *inter alia*, Galderma Labs., Galderma S.A., Dermalogix, Panda, and University with notice that it submitted its ANDA and a paragraph IV certification to the '920 and '100 patents. This notice included a detailed statement setting forth factual and legal bases as to why the '920 and '100 patent claims will not be infringed by the manufacture, use, offer for sale, sale, or importation of the clobetasol

propionate spray, 0.05% product described in Perrigo Israel's ANDA. Perrigo Israel's notice letter also detailed why the '920 and '100 patents are invalid, and, *inter alia*, expressly reserved the right to raise unenforceability in the event that suit was filed on the '920 and/or '100 patents. Further, Perrigo Israel's notice letter contained an Offer of Confidential Access to the ANDA.

36. The clobetasol propionate spray, 0.05% product described in Perrigo Israel's ANDA does not infringe any valid or enforceable claim of the '920 patent.

37. The clobetasol propionate spray, 0.05% product described in Perrigo Israel's ANDA does not infringe any valid or enforceable claim of the '100 patent.

38. Upon receipt of Perrigo Israel's notice of paragraph IV certification to the '920 and '100 patents, Galderma Labs., Galderma S.A. and Dermalogix sued Perrigo Israel for infringement of the '920 patent in this District. Perrigo Israel was not sued within the 45-day period described in 21 U.S.C. § 355(j)(5)(B)(iii) for alleged infringement of the '100 patent.

39. Because the '100 patent is listed in the Orange Book for clobetasol propionate spray, 0.05%, Perrigo Israel suffers a direct, concrete legal injury.

Counterclaim I
Declaration of Non-Infringement of the '920 Patent

40. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-39.

41. A present, genuine, and justiciable controversy exists between Galderma Labs., Galderma S.A., Dermalogix and Perrigo Israel regarding, *inter alia*, the issue of whether the manufacture, use, offer for sale, or sale of Perrigo Israel's clobetasol propionate spray, 0.05% product described in Perrigo Israel's ANDA would infringe any valid or enforceable claim of the '920 patent.

42. The manufacture, use, offer for sale, or sale of Perrigo Israel's clobetasol propionate spray, 0.05% product described in Perrigo Israel's ANDA would not infringe any valid or enforceable claim of the '920 patent.

43. Perrigo Israel is entitled to a declaration that the manufacture, use, offer for sale, or sale of its propionate spray, 0.05% product described in its ANDA would not infringe any valid or enforceable claim of the '920 patent.

Counterclaim II
Declaration of Invalidity of the '920 Patent

44. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-43.

45. A present, genuine, and justiciable controversy exists between Galderma Labs., Galderma S.A., Dermalogix and Perrigo Israel regarding, *inter alia*, the invalidity of the '920 patent.

46. The '920 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

47. Perrigo Israel is entitled to a declaration that the '920 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

Counterclaim III
Declaration of Non-Infringement of Claims of the '100 Patent

48. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-47.

49. A present, genuine, and justiciable controversy exists between Panda, University, Galderma Labs., Galderma S.A. and Perrigo Israel regarding, *inter alia*, the issue of whether the

manufacture, use, offer for sale, or sale of Perrigo Israel's clobetasol propionate spray, 0.05% product described in its ANDA would infringe any valid or enforceable claim of the '100 patent.

50. The manufacture, use, offer for sale, or sale of Perrigo Israel's clobetasol propionate spray, 0.05% product described in its ANDA would not infringe any valid or enforceable claim of the '100 patent.

51. Perrigo Israel is entitled to a declaration that the manufacture, use, offer for sale, or sale of its clobetasol propionate spray, 0.05% product described in its ANDA would not infringe claims of the '100 patent.

Counterclaim IV
Declaration of Invalidity of the '100 Patent

52. Perrigo Israel realleges and incorporates by reference the allegations of paragraphs 1-51.

53. A present, genuine, and justiciable controversy exists between Panda, University, Galderma Labs., Galderma S.A. and Perrigo Israel regarding, *inter alia*, the invalidity of the '100 patent.

54. The '100 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

55. Perrigo Israel is entitled to a declaration that the '100 patent is invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

JURY DEMAND

Defendants hereby demand a trial by jury as to all issues so triable.

REQUEST FOR RELIEF

WHEREFORE, Defendants request that this Court enter a Judgment and Order in their favor and against Plaintiffs/Counterclaim-Defendants Galderma Laboratories, Inc.,

Galderma S.A., Dermalogix Partners, Inc. and Counterclaim-Defendants Panda Pharmaceuticals, L.L.C. and The University of Tennessee Research Foundation as follows:

(a) declaring that the manufacture, sale, offer for sale, use or importation of the clobetasol propionate spray, 0.05% product described in Perrigo Israel's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '920 patent;

(b) declaring that the manufacture, sale, offer for sale, use or importation of the clobetasol propionate spray, 0.05% product described in Perrigo Israel's ANDA does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '100 patent;

(c) declaring that the '920 patent is invalid;

(d) declaring that the '100 patent is invalid;

(e) ordering that Plaintiffs' complaint be dismissed with prejudice and judgment entered in favor of Defendants;

(f) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Defendants attorney fees, costs, and expenses in this action; and

(g) awarding Defendants any further and additional relief as the Court deems just and proper.

Dated: February 4, 2010

Respectfully submitted,

By: /s/ Jane Politz Brandt w/permission

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CERTIFICATE OF SERVICE

On February 4, 2010, true and correct copies of the foregoing document were served in compliance with Local Rule 5.1 and have been served on all counsel who have consented to electronic service and all other counsel by regular mail.

/s/ Matthew P. Harper
Matthew P. Harper